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SEP 10 2003

#16

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,153,222. The application was filed on July 8, 2002, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703) 872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Stephen B. Maebius
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Washington Harbour, Suite 500
3000 K Street NW
Washington DC 20007-5109

RE: REMODULIN® (Trepstinil sodium)
Docket No. 03E-0245